

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA**

**IN RE: AVANDIA MARKETING, SALES
PRACTICES AND PRODUCTS LIABILITY
LITIGATION**

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**MDL No. 1871
07-MD-01871-CMR**

**THIS DOCUMENT APPLIES TO:
ALL ACTIONS**

**PLAINTIFFS' EXPEDITED MOTION AND MEMORANDUM OF LAW TO STRIKE
GLAXOSMITHKLINE'S MOTIONS TO EXCLUDE EXPERT TESTIMONY AND ITS
'OVERVIEW MEMORANDUM'**

COME NOW Plaintiffs, by and through their undersigned counsel, and respectfully move this Court to strike Defendant GlaxoSmithKline's ("GSK's") motions to exclude expert testimony and GSK's "Overview Memorandum on *Daubert* Issues Relating to General Causation"; and to extend Plaintiffs' deadline in which to respond to GSK's briefing by one week. In light of rapidly approaching deadlines, Plaintiffs additionally request that the Court expedite ruling on this motion. In support of its motion, Plaintiffs state as follows:

I. Introduction

On August 2, 2010, this Court entered an Order granting the parties' Joint Stipulation to Extend Page Limitations to thirty pages with respect to particular motions. (Joint Stipulation to Extend Page Limitations, Exhibit A). Defendant GlaxoSmithKline ("GSK") then disregarded that Court Order by filing a document that a) was not a motion at all; b) substantially exceeded thirty pages; and c) was incorporated by reference into all of GSK's motions to exclude expert testimony under Rule 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) (hereinafter "Daubert motions"). The document, called "GlaxoSmithKline's Overview Memorandum on *Daubert* Issues Relating to General Causation," requests no relief from the

Court. The document is nothing more additional argument in support of GSK's individual *Daubert* motions. Because those individual *Daubert* motions incorporate the Overview Memorandum, all of GSK's *Daubert* motions exceed the Court-ordered thirty-page limit. The Court, therefore, should strike all of GSK's motions. At the very least, the Court should strike GSK's "Overview Memorandum," both because it is not a proper motion and because it exceeds the Court's page limitations. In the absence of an immediate and favorable ruling as to the Overview Memorandum, Plaintiffs also request an additional week to respond to GSK's *Daubert* motions. Finally, should the Court deny Plaintiffs' Motion to Strike, Plaintiffs request an Order granting permission to file a similar Overview Statement, with a page limitation of no less than fifty pages.

II. Background

Under the Policies and Procedures issued by the Court, motions other than summary judgment motions are limited to fifteen pages. (*See* Policies and Procedures, Exhibit B, Item No. 7). However, at the request of GSK's counsel, the PSC agreed to request an Order from the Court allowing briefs to be no more than thirty pages. GSK then filed ten individual *Daubert* motions, supported by GSK's fifty-three page Overview Memorandum, which includes forty-seven pages of argument drafted by GSK's attorneys. (*See generally* GSK Overview Memorandum, Exhibit C). The document does not purport to seek any relief from the Court, and it is not titled as a "motion."

As early as the second sentence of the Memorandum, GSK asks this Court to exclude all of Plaintiffs' general causation experts. (GSK Memo, Exhibit C, at 1). GSK's Memorandum then launches immediately into argument against Plaintiffs' experts. For instance, the Memorandum lists specific reasons why, in GSK's mind, the opinions of Plaintiffs' Experts are

all unreliable. (*Id.* at 3-4). The Memorandum lays out the *Daubert* standards and offers argument regarding the burden of proof. (*Id.* at 7-8). From there, the Memorandum goes into an analysis of why certain epidemiological studies are more reliable than other epidemiological studies – in both specific and general terms. (*Id.* at 9-21). The Memorandum discusses randomized controlled trials (“RCTs”) and observational studies. (*Id.* at 9-10). Specifically, the Memorandum talks about the virtues of trials named RECORD, DREAM and ADOPT, and attacks the Nissen Meta-Analysis. (*Id.* at 13-18). Then, the Memorandum starts attacking specific experts, citing to the experts’ deposition testimony. (*Id.* at 22). GSK also attacks the standards employed by Plaintiffs’ experts, as well as their opinions on the mechanism of action. (*Id.* at 23-25). GSK then makes a short argument related to atherosclerosis, and that’s the end of the brief ... except that it’s not. GSK has three additional sections that it labels as Appendix I, II and III.

The first “Appendix” talks about epidemiological studies in general terms. This “Appendix” compares RCTs to observational studies. (*Id.* at I-1 - I-2). The second “Appendix” discusses specific studies, extolling the virtues of trials named RECORD, DREAM and ADOPT, and attacking the Nissen Meta-Analysis. (II-1 - II-6). Both of those sections address issues, and even specific studies, that are also addressed in the Argument portion of the brief. Finally, in “Appendix III” GSK lays out the views of other organizations regarding trials already discussed, such as RECORD and the Nissen Meta-Analysis. (III-1 - III-2). Nowhere in any section labeled as an “Appendix” is there any material produced by an outside source. GSK’s lawyers wrote every word.

GSK did not simply file its Overview Memorandum as a separate document unrelated to its individual *Daubert* motions. Instead, GSK incorporated the entire forty-seven pages of

argument by reference into every *Daubert* motion that it filed.¹ Additionally, GSK cited specific portions of the Overview Memorandum throughout its motions. Therefore, GSK's individual *Daubert* motions all vastly exceed thirty pages and should be struck. In addition, the Overview Memorandum itself exceeds thirty pages, and if the Court declines to strike GSK's individual *Daubert* motions, it should strike the Overview Memorandum.

III. All of GSK's *Daubert* Motions Exceed the 30-Page Limit Imposed by the Court, as Does the Overview Memorandum by Itself

A. The Court Has the Discretion to Strike GSK's Motions

A district court has the discretion to reject a submission where the party making the submission fails to comply with local rules. *See Emerick v. U.S. Suzuki Motor Corp.*, 750 F.2d 19, 21 (3d Cir. 1984) (affirming district court's decision to exclude expert and videotaped testimony where proponent did not comply with notice requirements). Where a party violates local rules, the party must show "good cause" that the Court should accept its submission. *Id.* Specifically, the Court has the discretion to reject filings that exceed applicable page limits. *See Weiss v. York Hosp.*, 628 F. Supp. 1392, 1403 (M.D. Pa. 1986).

In *Weiss* – a decision regarding attorney's fees – the district court described the case history, including briefing to the Court of Appeals. The defendants filed motion requesting that the Court of Appeals raise its page limit for an appellate brief from fifty to eighty-five pages. *Id.* The Clerk then entered an Order allowing a sixty-five page submission. Unfazed, the defendants filed ninety-six pages of briefing, divided into two briefs that each incorporated the other by reference. *Id.* Before the plaintiff even filed a motion to strike, the Clerk rejected the filing.

¹ GSK **incorporates** by reference its entire Overview Memorandum by reference in Footnote 1 on Page 1 of its motions to exclude the following expert witnesses: Dr. Donald Austin, Dr. Eliot Brinton, Dr. Joshua Septimus, Dr. Stephen Lippman, Dr. John Gueriguian, Dr. Brian Swirsky, Dr. Nicholas Jewell, Dr. Allan Sniderman and Dr. Peter Rost. In its motion to exclude Dr. Nicholas Depace, GSK incorporates the Overview Memorandum by reference in Footnote 58 on Page 14.

The defendants then filed a motion to the Court of Appeals, requesting that it overrule the Clerk's decision; the court denied the motion. *Id.*

B. GSK's Overview Memorandum Exceeds the Page Limitations by Itself

GSK's Overview Memorandum contains a twenty-seven page argument section and twenty pages that purport to be "Appendixes." However, the Memorandum contains forty-seven pages of argument, and therefore this Court should treat the Memorandum as a forty-seven page submission. *See Thoma v. A.H. Robins Co.*, 100 F.R.D. 344, 347 (D.N.J. 1983). In *Thoma*, the Court struck a brief in part because it exceeded a thirty-page limitation. Although the Argument section purported to be thirty pages long, the Court treated the brief as containing thirty-seven pages because "the other parts of the brief engage in discussion which would more properly be in the Argument section." *Id.* As in *Thoma*, this Court should reject GSK's effort to bring the Memorandum within the perceived thirty-page limit.

As explained above, GSK makes extremely similar arguments in the main section of its brief and in the Appendixes. The Argument section discusses epidemiological studies generally, and so does "Appendix I." The Argument section compares specific studies, and so does "Appendix II." "Appendix III" contains additional argument about the studies. In addition, nothing in the Appendixes derives from another source. GSK's attorneys wrote all three "Appendixes." There is no logical basis for dividing GSK's Overview Memorandum in the way that GSK has organized it. The only plausible explanation is that GSK was trying to evade the Court's rules. The Memorandum was artificially divided in the hope that the Court would excuse GSK's unwillingness to comply with the Court's rules. The Memorandum should be stricken as it exceeds even the Court Ordered enlarged page limits.

C. *Incorporating the Memorandum Causes All of GSK's Daubert Motions to Exceed the Court-Ordered Page Limitation*

In addition, every one of GSK's individual *Daubert* motions incorporates the Overview Memorandum by reference. According to the Black's Law Dictionary, "incorporation by reference" means: "A method of making a secondary document part of a primary document by including in the primary document a statement that the secondary document should be treated as if it were contained within the primary one." Black's Law Dictionary 834 (9th ed. 2009). (emphasis added). As discussed above, GSK's Overview Memorandum should be treated as a forty-seven page document. But even accepting GSK's artificial divisions, the Overview Memorandum is at least twenty-seven pages long. Consequently, when the Memorandum is "incorporated by reference," making it a part of each individual *Daubert* motion, every *Daubert* motion is far in excess of the Court's page limits.

Specifically, the motion to exclude Dr. Eliot Brinton contains twenty-nine pages of argument, incorporates the full forty-seven page Memorandum, and specifically references twelve pages – a total of eighty-eight pages. The motion to exclude Dr. Allan Sniderman includes twenty-two pages of argument, incorporates the full Memorandum, and specifically references nine pages – a total of seventy-eight pages. The motion to exclude Dr. Joshua Septimus includes twenty-eight pages of argument, incorporates the full Memorandum, and specifically references GSK's entire discussion of long-term clinical trials – a total of approximately ninety-eight pages.² The motion to exclude Dr. Stephen Lippman includes nineteen pages of argument, incorporates the full Memorandum, and specifically references sixty-six total pages in an additional seven citations – a total of 132 pages. The motion to exclude Dr. John Gueriguian includes thirty pages of argument and incorporates the full

² That estimate counts Pages 12-21 of GSK's Argument section and all of "Appendix II."

Memorandum, a total of seventy-seven pages. The motion to exclude Dr. Brian Swirsky includes twenty-eight pages of argument, incorporates the full Memorandum, and specifically references Appendix II (thirteen pages) another four times, for a total of 127 pages. The motion to exclude Dr. Nicholas Depace includes twenty-three pages of argument, incorporates the full Memorandum, and specifically references another eleven pages, a total of seventy-nine pages. The motion to exclude Dr. Nicholas Jewell includes twenty-five pages of argument, incorporates the full Memorandum, and specifically references another eighteen pages, a total of ninety pages. The motion to exclude Dr. Donald Austin includes twenty-one pages of argument, incorporates the full Memorandum, and specifically references another twenty-two pages, a total of ninety pages. Finally, the motion to exclude Dr. Peter Rost includes twenty pages of argument and incorporates the full Memorandum, a total of sixty-seven pages. Even if the Court excludes the additional citations to specific portions of the Overview Memorandum, all of GSK's *Daubert* motions contain at least sixty-six pages – nineteen pages of argument plus the forty-seven page Memorandum.

These gigantic motions are extremely prejudicial to Plaintiffs, who must respond to numerous *Daubert* motions – and also to numerous motions in state court – in an extremely short period of time. The Overview Memorandum is not a document that an attorney responding to an individual *Daubert* motion can simply ignore – nor was intended to be one. In the second sentence, GSK makes it clear that the document lends support to its arguments against individual experts. (GSK Memo at 1).³ As described in Section II, the arguments in GSK's Overview Memorandum are exactly the kind of arguments a party would be expected to make in a *Daubert* motion. For instance, GSK's Memorandum lists several reasons why it asserts that all of

³ The Overview Memorandum purports to support GSK's motions against Plaintiffs' seven "general causation" experts, but GSK incorporates the Memorandum by reference in its motions against all ten of Plaintiffs' experts.

Plaintiffs' experts are unreliable, and then expounds upon those arguments; it lays out its conception of the legal standards under *Daubert*; it makes an argument about the burden of proof; it goes into depth about epidemiological studies generally and compares specific studies to one another; and perhaps most importantly, the Memorandum specifically attacks the opinions of Plaintiffs' experts, some of them by name. The Memorandum also attacks the methodology of Plaintiffs' experts, and the mechanism of action that they describe.

If the Court allows GSK's briefing to stand, the prejudice to Plaintiffs will be immense. Given the nature of GSK's Memorandum, each response brief submitted by Plaintiffs would have to respond to at last sixty-six pages of arguments by GSK, with only thirty pages in which to do so. This situation is made worse by the fact that GSK's counsel expressly reached out to PSC members to request an agreement to enlarge the page limits to thirty pages. The PSC agreed to what seemed like a reasonable request, only to be blind-sided by the Overview Memorandum. Clearly, the Court should take action to prevent GSK from benefiting from its flouting the Court's rules. The only real issue the most appropriate action to take, given the Court's discretion in addressing the issue.

IV. The Court Should Strike All of GSK's Daubert Motions; Alternatively, the Court Should Strike GSK's Overview Memorandum

Because of GSK's knowing disregard for the Court's briefing rules, the Court should strike all of GSK's *Daubert* motions on the ground that GSK far exceeded the Court's page limitations. Certainly, striking all of GSK's motions would be an extreme remedy, but the circumstances justify such action. First, GSK did not simply exceed the Court's limits by a page or two. As explained above, every one of GSK's *Daubert* motions is more than double the size allowed by the Court, once the Overview Memorandum is incorporated. Second, GSK tried to deceive the Court by presenting forty-seven pages of argument as a twenty-seven page

submission with “Appendixes.” Third, GSK took all of these steps after both Plaintiffs and the Court accommodated GSK’s wish to increase the normal page limit from fifteen pages to thirty pages. That Order left GSK with 300 pages in which to make its points in ten *Daubert* motions, and yet GSK was unwilling or unable to work within those expansive confines. Fourth, GSK did not seek the Court’s permission to exceed the Court’s briefing limits.

Finally, the prejudice to Plaintiffs is extreme in this situation. GSK of course had months to draft and craft its motions and the Memorandum, and Plaintiffs have two weeks within which to respond. Now, in addition to responding to all of these motions, plus a summary judgment motion, plus corresponding motions in state court, Plaintiffs are faced with responding to a forty-seven page document that does not ask for relief. In addition, Plaintiffs’ attorneys drafting individual *Daubert* responses must respond to approximately seventy or eighty pages of argument in each motion within the Court-ordered thirty-page limit. For all of these reasons, striking every one of GSK’s *Daubert* motions would be an appropriate remedy. GSK should be held accountable for its blatant disregard of the Court’s briefing rules, and the Court should not allow Plaintiffs to be prejudiced by GSK’s subterfuge.

If the Court feels that remedy would be too harsh, however, the Court should at least strike GSK’s Overview Memorandum. First, the Overview Memorandum is not a proper motion. Nothing in the Court’s Rules contemplates such a document. According to this Court’s Policies and Procedures, the Court “follows the requirements of Local Rule of Civil Procedure 7.1.” (Exhibit B, Item No. 7). According to Rule 7.1 of the Eastern District of Pennsylvania’s Local Rules, every motion must include a Proposed Order describing the relief requested. E.D. Pa. Loc. R. Civ. P. 7.1(a). There is no provision in the Rules for a motion or other briefing document that does not seek any relief. *See id.* GSK’s Memorandum did not include such a

Proposed Order, and it did not request any relief. As such, the Memorandum was not in compliance with the Court's Rules and should be stricken.

Even if the Court somehow concludes that such a brief could be proper, the Court should strike GSK's Overview Memorandum because it grossly exceeds the Court's page limitations. GSK's chicanery suggests that GSK was trying to fit the Memorandum within a thirty-page window, but in reality the limit on such a filing would be fifteen pages. The Court's general policy is that motions are limited to fifteen pages. (*See* Exhibit B, Item No. 7). The Joint Stipulation entered into on August 2 expanded the limitation to thirty pages for "motions to exclude expert testimony under Fed. R. Evid. 702 and *Daubert* submitted by the parties, and any Response, Reply and Sur-reply memoranda filed thereto." (Exhibit A). The Overview Memorandum does not purport to be any of these things. It is not a motion to exclude testimony, and it clearly does not respond or reply to anything filed by Plaintiffs. Consequently, the general fifteen-page rule applies.

Of course, that distinction only matters if the Court accepts GSK's ridiculous division of the Memorandum into Argument and three "Appendixes." The Memorandum contains forty-seven pages of legal argument, drafted by GSK's lawyers. In addition, the "Appendixes" address subjects that are also addressed in the Argument section. Simply put, the Memorandum is a forty-seven page brief, and therefore it exceeds even the thirty-page limitation.

Striking the Overview Memorandum would hold GSK accountable for disregarding the Court's rules, and it would significantly reduce the prejudice to Plaintiffs. GSK could not be prejudiced by being compelled to comply with an Order of the Court that it requested, especially when GSK had 300 pages in which to make its *Daubert* arguments in individual motions. In addition, striking the Overview Memorandum – and striking references to it in GSK's individual

Daubert motions – would bring GSK’s individual *Daubert* motions within the thirty-page limit mandated by this Court’s Rules. For all of these reasons, this Court should strike GSK’s Overview Memorandum if it decides not to strike all of GSK’s *Daubert* motions.

V. Timing Issues

GSK’s willingness to flout the Court’s Rules has already prejudiced Plaintiffs, in that their counsel have had to spend time on this Motion to Strike and have had to consider the Overview Memorandum in preparing responses to individual *Daubert* motions. Each day that this Motion remains unresolved, the prejudice to Plaintiffs increases. Until Plaintiffs receive a favorable ruling on this Motion, they must assume that all of GSK’s briefing will remain in the case.

Should the Court immediately grant either of Plaintiffs’ requests for relief – by Monday, August 16 – Plaintiffs will have enough time to adjust and meet all previously imposed deadlines. However, in the absence of an immediate and favorable ruling, Plaintiffs request an additional week to respond to GSK’s *Daubert* motions due to the prejudice they will suffer without such relief. Every day that this issue remains in flux, Plaintiffs must prepare a response to the forty-seven page Overview Memorandum, and must consider the Overview Memorandum in each of their individual *Daubert* responses. Additionally, should the Court fail to strike GSK’s Overview Memorandum, Plaintiffs request an Order specifically granting them the opportunity to file a similar document, with a page limitation of no less than fifty pages. The fairness of such an Order should be self-evident under the circumstances.

VII. Conclusion

For the foregoing reasons, Plaintiffs respectfully request that the Court grant this Motion and strike all of GSK’s *Daubert* motions. In the alternative, Plaintiffs request that the Court

strike GSK's Overview Memorandum. Additionally, in the absence of an immediate and favorable ruling, Plaintiffs request an additional week to respond to GSK's *Daubert* motions. Finally, should the Court deny Plaintiffs' motion to strike, Plaintiffs request an Order expressly granting Plaintiffs leave to file a similar document of no less than fifty pages.

Dated: August 13, 2010

Respectfully submitted,

/s/Thomas P. Cartmell

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CERTIFICATE OF SERVICE

I hereby certify that on August 13, 2010, I caused a true and correct copy of the foregoing Plaintiff Steering Committee's Motion and Memorandum of Law in Support of Motion To Strike GlaxoSmithKline's Overview Memorandum on *Daubert* Issues Relating to General Causation, to be served with the Court and by electronic mail and Federal Express upon defense counsel as follows:

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